

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

**IN RE: Acetaminophen – ASD-ADHD Products Liability
Litigation**

Docket No. 22-md-3043 (DLC)

This Document Relates To: *All Cases*

**DECLARATION OF ASHLEY C. KELLER
IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS'
MOTION TO EXCLUDE THE OPINIONS OF DR. ROBERTA NESS**

1. My name is Ashley C. Keller, and I am a partner at Keller Postman, LLC. I am Co-Lead Counsel for the Plaintiffs in this MDL. I declare under penalty of perjury that the below is true and correct.
2. Attached hereto as **Exhibit 1** is a true and correct copy of *Curriculum Vitae* of Roberta B. Ness, MD, M.P.H. Plaintiffs served this document on Defendants on February 7, 2024, in connection with this action.
3. Attached hereto as **Exhibit 2** is a true and correct copy of Materials Considered of Roberta B. Ness, MD, M.P.H. Plaintiffs served this document on Defendants on February 7, 2024, in connection with this action.
4. Attached hereto as **Exhibit 3** is a true and correct copy of the handwritten notes, which were Exhibit 5 to the April 9, 2024 deposition of Roberta B. Ness.
5. Attached hereto as **Exhibit 4** is a true and correct copy of excerpts of the September 7, 2023 deposition transcript of Stephen Faraone.
6. Attached hereto as **Exhibit 5** is a true and correct copy of excerpts of the September 1, 2023 deposition transcript of Alexander Kolevzon.
7. Attached hereto as **Exhibit 6** is a true and correct copy of excerpts of the September 6, 2023 deposition transcript of Jennifer Pinto-Martin.

8. Attached hereto as **Exhibit 7** is a true and correct copy of excerpts of the August 28, 2023 deposition transcript of Craig Powell.

9. Attached hereto as **Exhibit 8** is a true and correct copy of excerpts of the May 25, 2023 deposition transcript of Carolyn Jeffcoat.

10. Attached hereto as **Exhibit 9** is a true and correct copy of Stephen V. Faraone, *An Overview of Attention Deficit Hyperactivity Disorder*, Slide Presentation (2022), which was Exhibit 771 to the September 7, 2023 deposition of Stephen Faraone.

11. Attached hereto as **Exhibit 10** is a true and correct copy of Stephen V. Faraone et al., *The World Federation of ADHD International Consensus Statement: 208 Evidence-Based Conclusions About the Disorder*, 128 *Neuroscience & Biobehavioral Revs.* 789 (2021), which was Exhibit 781 to the September 7, 2023 deposition of Dr. Stephen Faraone.

12. Attached hereto as **Exhibit 11** is a true and correct copy of National Center for Toxicological Research, Science Advisory Board Meeting Tr., (May 19, 2022), which was Exhibit 622 to the September 6, 2023 deposition of Dr. Jennifer Pinto-Martin.

13. Attached hereto as **Exhibit 12** is a true and correct copy of ChemRisk, *Draft Overview of Toxicological Data and Assessment of Paracetamol (Acetaminophen)* (Feb. 8, 2023), which was Exhibit 216 to the August 28, 2023 deposition of Dr. Craig Powell.

14. Attached hereto as **Exhibit 13** is a true and correct copy of Johnson & Johnson Consumer Inc., *Draft Review of Nonclinical Endocrine, Developmental, and Reproductive Data on Acetaminophen* Slide Presentation (2022).

15. Attached hereto as **Exhibit 14** is a true and correct copy of Project Cocoon Update, Slide Presentation (Jan. 20, 2023), which Johnson & Johnson Consumer, Inc. produced as bates-stamp APAP-JJCI-0000518704.

16. Attached hereto as **Exhibit 15** is a true and correct copy of Agency for Toxic Substances and Disease Registry, *ATSDR Assessment of the Evidence for the Drinking Water Contaminants at Camp Lejeune and Specific Cancers and Other Diseases* (Jan. 13 2017).

17. Attached hereto as **Exhibit 16** is a true and correct copy of F. Barone Adesi et al., Abstract, *Duration as a Proxy for Cumulative Exposure: Should We Trust Positive Results?*, 332 Occupational & Env't Med. A113 (2013) .

18. Attached hereto as **Exhibit 17** is a true and correct copy of Silvia Alemany et al., *Prenatal and Postnatal Exposure to Acetaminophen in Relation to Autism Spectrum and Attention-Deficit and Hyperactivity Symptoms in Childhood: Meta-analysis in Six European Population-Based Cohorts*, 36 Eur. J. Epidemiology 993 (2021), which was Exhibit 612 to the September 6, 2023 deposition of Dr. Jennifer Pinto-Martin.

19. Attached hereto as **Exhibit 18** is a true and correct copy of Valentin Amrhein et al., *Retire Statistical Significance*, 567 Nature 305 (2019).

20. Attached hereto as **Exhibit 19** is a true and correct copy of Nazzareno Ballatori et al., *Glutathione Dysregulation and The Etiology and Progression of Human Diseases*, 390 Biological Chemistry 191 (2009).

21. Attached hereto as **Exhibit 20** is a true and correct copy of Ann Z. Bauer et al., *Prenatal Paracetamol Exposure and Child Neurodevelopment: A Review*, 101 Hormonal Behav. 125 (2018), which was Exhibit 618 to the September 6, 2023 deposition of Dr. Jennifer Pinto-Martin.

22. Attached hereto as **Exhibit 21** is a true and correct copy of Ridwan Opeyemi Bello et al., *Does Human Papillomavirus Play a Causative Role in Prostate Cancer? A Systematic Review Using Bradford Hill's Criteria*, 15 Cancers 1 (2023).

23. Attached hereto as **Exhibit 22** is a true and correct copy of Andréa D. Bertoldi et al., *Associations of Acetaminophen Use During Pregnancy and the First Year of Life With Neurodevelopment in Children*, 34 *Paediatric & Perinatal Epidemiology* 267 (2020).

24. Attached hereto as **Exhibit 23** is a true and correct copy of C.G. Bornehag et al., *Prenatal Exposure to Acetaminophen and Children's Language Development at 30 Months*, 51 *Eur. Psychiatry* 98 (2018).

25. Attached hereto as **Exhibit 24** is a true and correct copy of Frank Bove, *Evaluation of Cancer Incidence Among Marines and Navy Personnel and Civilian Workers Exposed to Contaminated Drinking Water at USMC Base Camp Lejeune: A Cohort Study*, ATSDR/CDC (2024).

26. Attached hereto as **Exhibit 25** is a true and correct copy of Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 *Procs. Royal Soc'y Med.* 295 (1965), which was Exhibit 631 to the September 6, 2023 deposition of Dr. Jennifer Pinto-Martin.

27. Attached hereto as **Exhibit 26** is a true and correct copy of Terrence Davidson et al., *The Bradford Hill Criteria and Zinc-Induced Anosmia*, 136 *Archives Otolaryngology Head Neck Surgery* 673 (2010).

28. Attached hereto as **Exhibit 27** is a true and correct copy of Phyllis A. Dennery, *Effects of Oxidative Stress on Embryonic Development*, 81 *Birth Defects R* 155 (2007).

29. Attached hereto as **Exhibit 28** is a true and correct copy of Kim Do et al., *Redox Dysregulation Neurodevelopment, and Schizophrenia*, 19 *Current Op. Neurobiology* 220 (2009).

30. Attached hereto as **Exhibit 29** is a true and correct copy of Kristen Fedak et al., *Applying the Bradford Hill Criteria in the 21st Century: How Data Integration Has Changed Causal Inference in Molecular Epidemiology*, 12 *Emerging Themes in Epidemiology* 1 (2015).

31. Attached hereto as **Exhibit 30** is a true and correct copy of Kristina Gervin et al., *Long-term Prenatal Exposure to Paracetamol is Associated with DNA Methylation Differences in Children Diagnosed with ADHD*, 9 Clinical Epigenetics 1 (2017).

32. Attached hereto as **Exhibit 31** is a true and correct copy of Daniela Giustarini et al., *How to Increase Cellular Glutathione*, 12 Antioxidants 1 (2023).

33. Attached hereto as **Exhibit 32** is a true and correct copy of the Supporting Information to Kristin Gustavson et al., *Acetaminophen Use During Pregnancy and Offspring Attention Deficit Hyperactivity Disorder – A Longitudinal Sibling Control Study*, 1 JCPP Advances 1 (2021), which was Exhibit 628 to the September 6, 2023 deposition of Dr. Jennifer Pinto-Martin.

34. Attached hereto as **Exhibit 33** is a true and correct copy of Jason M. Hansen et al., *Valproic Acid Promotes SOD2 Acetylation: A Potential Mechanism of Valproic Acid-Induced Oxidative Stress in Developing Systems*, 55 Free Radical Resch. 1130 (2021).

35. Attached hereto as **Exhibit 34** is a true and correct copy of Yuelong Ji et al., *Association of Cord Plasma Biomarkers of In Utero Acetaminophen Exposure With Risk of Attention-Deficit/Hyperactivity Disorder and Autism Spectrum Disorder in Childhood*, 77 JAMA Psychiatry 180 (2020).

36. Attached hereto as **Exhibit 35** is a true and correct copy of E.S. Johnson, *Duration of Exposure as a Surrogate For Dose in the Examination of Dose Response Relations*, 43 Brit. J. Med. 427 (1986).

37. Attached hereto as **Exhibit 36** is a true and correct copy of Nidhin Joseph et al., *Oxidative Stress and ADHD: A Meta-Analysis*, 19 J. Attention Disorders 915 (2015), which was Exhibit 785 to the September 7, 2023 deposition of Stephen Faraone.

38. Attached hereto as **Exhibit 37** is a true and correct copy of Nayla Khoury et al., *From Structural Disparities to Neuropharmacology: A Review of Adult Attention-Deficit/Hyperactivity Disorder Medication Treatment*, 31 Child & Adolescent Psychiatric Clinics of N. Am. 343 (2022), which was Exhibit 784 to the September 7, 2023 deposition of Stephen Faraone.

39. Attached hereto as **Exhibit 38** is a true and correct copy of Young Ran Kim et al., *Health Consequences of Exposure to Brominated Flame Retardants: A Systematic Review*, 106 Chemosphere 1 (2014).

40. Attached hereto as **Exhibit 39** is a true and correct copy of excerpts from Timothy Lash et al., *Modern Epidemiology* (4th ed. 2021).

41. Attached hereto as **Exhibit 40** is a true and correct copy of Hannah E. Laue et al., *Association Between Meconium Acetaminophen and Childhood Neurocognitive Development in GESTE, a Canadian Cohort Study*, 167 Toxicological Scis. 138 (2019).

42. Attached hereto as **Exhibit 41** is a true and correct copy of James S. Lawson et al., *Mouse Mammary Tumour Virus (MMTV) in Human Breast Cancer—The Value of Bradford Hill Criteria*, 14 Viruses 1 (2022).

43. Attached hereto as **Exhibit 42** is a true and correct copy of Richard J. McNally, *Memory and Anxiety Disorders*, 352 Phil. Transactions Royal Soc’y London B 1755 (1997).

44. Attached hereto as **Exhibit 43** is a true and correct copy of Christopher J. Nowinski et al., *Applying the Bradford Hill Criteria for Causation to Repetitive Head Impacts and Chronic Traumatic Encephalopathy*, 13 Frontiers Neurology 1 (2022).

45. Attached hereto as **Exhibit 44** is a true and correct copy of Dhyanesh Patel et al., *Ethanol (E) Impairs Fetal Brain GSH Homeostasis by Inhibiting Excitatory Amino-Acid Carrier 1 (EAAC1)-Mediated Cysteine Transport*, 18 Int'l J. Molecular Sci. 1 (2017).

46. Attached hereto as **Exhibit 45** is a true and correct copy of Gaëtan Philippot et al., *Paracetamol (Acetaminophen) and its Effect on the Developing Mouse Brain*, 4 Frontiers in Toxicology 1 (2022).

47. Attached hereto as **Exhibit 46** is a true and correct copy of Luciana Tovo-Rodrigues et al., *Low Neurodevelopmental Performance and Behavioural/Emotional Problems at 24 and 48 Months in Brazilian Children Exposed to Acetaminophen During Foetal Development*, 34 Padiatric Perinatal Epidemiology 278 (2020).

48. Attached hereto as **Exhibit 47** is a true and correct copy of Kelsey K. Wiggs et al., *Antiseizure Medication Use During Pregnancy and Risk of ASD and ADHD in Children*, 95 Neurology e3232 (2020), which was Exhibit 620 to the September 6, 2023 deposition of Jennifer Pinto-Martin.

Dated: May 28, 2024

Respectfully submitted,

KELLER POSTMAN LLC

/s/ Ashley C. Keller

Ashley C. Keller (IL Bar #1029118)*

KELLER POSTMAN LLC

150 N. Riverside Plaza, Suite 4100

Chicago, Illinois 60606

(312) 741-5220

ack@kellerpostman.com

*Admitted Pro Hac Vice

Attorney for Plaintiffs